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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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03/22/2005

In-San Kim

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8173

20311 7590 08/03/2007  
LUCAS & MERCANTI, LLP  
475 PARK AVENUE SOUTH  
15TH FLOOR  
NEW YORK, NY 10016

EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/528,749		KIM ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ernst V. Arnold		1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/6/07 has been entered.

Claims 2 and 6 have been cancelled. Claims 1, 3-5, 7 and 8 are under examination. The previous rejection of record is withdrawn in favor of the rejection below.

Comment: Please change the claim status of claim 8 to reflect the amendment.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al. (US 2002/0071827 Pub. Date: 06/13/2002) in view of Liu (US 5,281,265) and Zimmermann (US 6,692,563) and Walker (US 4,795,475).

Applicant claims a gel-type bone-filling composition for stimulating bone-formation and bone-consolidation comprising 1) 20 -80 weight% of mixture containing  $\text{CaSO}_4$  (98-99 weight%) and 0.3-1 weight % of  $\text{CaCO}_3$ , 0.3-1 weight % of  $\text{MgCO}_3$ , and 0.5-1 weight % of  $\text{CaCO}_3 \cdot \text{MgCO}_3$ ; and 2) 80-20 weight% of viscous biopolymer.

Please note that in the absence of evidence to the contrary the Examiner is interpreting  $\text{CaCO}_3 \cdot \text{MgCO}_3$  to be equivalent to  $\text{CaMg}(\text{CO}_3)_2$  which is also known as dolomite.

#### **Determination of the scope and content of the prior art**

##### **(MPEP 2141.01)**

Petersen et al. teach a bone graft substitute composition consisting essentially of calcium sulfate, a mixing solution and a plasticizing substance and a bone graft composition comprising calcium sulfate, demineralized bone matrix, cancellous bone, a plasticizing substance and a mixing solution (Claims 1 and 16). The plasticizing substance can be various biopolymers such as various celluloses including carboxymethylcellulose and ethyl cellulose, as well as hyaluronic acid (Claims 4, 7, and 19). Peterson et al. teach making injectable, paste and putty compositions, which the

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Examiner interprets to read upon gel-type (see page 4, [0056] and 0058], for example).

Petersen et al. teach a composition comprising about 80-120 parts by weight calcium sulfate and about 1 to about 40 parts by weight plasticizing agent (claim 23). Petersen et al. teach that the composition can contain 0.1-2 weight % sodium bicarbonate as well as other inorganic elements and inorganic salts thus establishing a guideline for the amount of carbonate salts to add to the composition (Page 2, [0019], page 4 [0051]).

Liu teaches the resorbable calcium sulfate surgical cements for use in medical applications such as orthopedic and maxillofacial surgeries and dental applications comprising a biocompatible filler component selected from the group consisting of calcium carbonate, magnesium carbonate and mixtures thereof (Claims 1, 15 and 16). Liu teaches the weight ratio of the fillers to the cementing components can be up to 4 to 1 (Column 4, lines 41-53). Liu states that biocompatible filler component is substantially inert (Column 4, lines 41-57; Column 5, line 35 and claims 15 and 16). Liu teaches a cement with mixtures of calcium carbonate, magnesium carbonate and other resorbable biocompatible materials (Claim 16).

Walker teaches that dolomite ( $\text{CaMg}(\text{CO}_3)_2$ ) and other minerals have been found to exhibit osteophilic properties (Column 2, lines 60-65).

Zimmermann teaches that resorbable materials like dolomite can be admixed in bone cement (Column 1, lines 63-65).

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

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1. Peterson et al. do not expressly teach a bone filling composition with 0.3-1 weight % of  $\text{CaCO}_3$ , 0.3-1 weight % of  $\text{MgCO}_3$ , and 0.5-1 weight % of  $\text{CaCO}_3 \cdot \text{MgCO}_3$  to the composition.

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a bone filling composition with 0.3-1 weight % of  $\text{CaCO}_3$ , 0.3-1 weight % of  $\text{MgCO}_3$ , and 0.5-1 weight % of  $\text{CaCO}_3 \cdot \text{MgCO}_3$ , as suggested by Liu, Zimmermann and Walker, to the composition of Petersen et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Petersen suggests the inclusion of inorganic elements and salts and Liu teaches that calcium carbonate, magnesium carbonate and other resorbable materials. Zimmermann provides the nexus teaching that dolomite is a resorbable material for use in bone cements. One of ordinary skill in the art would have been further motivated to add dolomite to the bone cement because Walker teaches that it is osteophilic. The adjustment of particular working conditions (e.g., determining an appropriate amount of  $\text{CaCO}_3$ ,  $\text{MgCO}_3$ ,  $\text{CaCO}_3 \cdot \text{MgCO}_3$  to add to the composition) is deemed merely a matter of routine optimization of the basic guidelines established by Petersen by one of ordinary skill in the art. It is the Examiner's position, in the absence of clear and convincing evidence to the contrary, that calcium sulfate renders obvious other hydrated forms of calcium sulfate.

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It is the Examiner's position that In the absence of any criticality/unexpected results, the presently claimed invention is considered *prima facie* obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserts that there is no motivation to combine the references and that "Applicant's respectfully draw the Examiner's attention to the fact that Liu et al., at most, discloses calcium carbonate as pertinent to the claimed invention.  $\text{MgCO}_3$  and  $\text{CaCO}_3$ - $\text{MgCO}_3$  are not described by Liu." The Examiner cannot agree. Liu et al. do teach and suggest mixtures of calcium carbonate and magnesium carbonate and other resorbable biocompatible materials (claim 16). Zimmermann establishes that dolomite

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(CaMg(CO<sub>3</sub>)<sub>2</sub>) is a resorbable material that can be used in bone cement. All of the components are taught in the art for the same purpose. It is then merely routine optimization of the components taught in the art to arrive at the instant invention in the absence of evidence to the contrary. The expected result from combining the components is a bone cement.

***Claim Rejections - 35 USC § 103***

Claims 1, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu (US 5,281,265) in view of Petersen et al. (US 2002/0071827 Pub. Date: 06/13/2002) and Zimmermann (US 6,692,563) and Walker (US 4,795,475).

Applicant claims a gel type bone-filling composition wherein the ratio of calcium sulfate to carboxymethylcellulose is 50:50.

**Determination of the scope and content of the prior art**

**(MPEP 2141.01)**

The cited references are discussed in detail above and those discussions are hereby incorporated by reference.

**Ascertainment of the difference between the prior art and the claims**

**(MPEP 2141.02)**

1. Liu do not expressly teach a composition wherein the ratio of calcium sulfate to carboxymethylcellulose is 50:50.

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make a bone filling composition of Liu wherein the ratio of calcium sulfate to carboxymethylcellulose is 50:50 and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Liu teach a ratio of filler to cementing components (calcium sulfate) can be up to about 4 to 1 which encompasses 1 to 1 or the instantly claimed ration of 50:50. Liu teaches that the filler can be mixtures of calcium carbonate, magnesium carbonate and other resorbable biocompatible materials. It is the Examiner's position that the other resorbable biocompatible materials encompass viscous biopolymers such as carboxymethylcellulose as well as dolomite. The references of Peterson et al., Walker and Zimmerman are relied upon to provide the teachings for the biocompatible materials.

It is then merely routine optimization of the components taught in the art to arrive at the instant invention in the absence of evidence to the contrary. The expected result from combining the components is a bone-filling cement.

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A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claims are allowed.

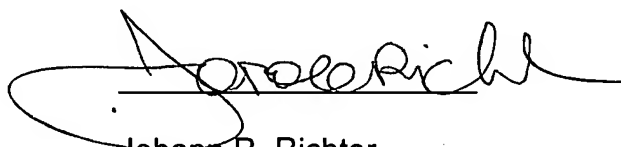
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold  
Patent Examiner  
Technology Center 1600  
Art Unit 1616

A handwritten signature in black ink, appearing to read "Johann R. Richter", written over a horizontal line.

Johann R. Richter  
Supervisory Patent Examiner  
Technology Center 1600